UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. 89,484 bottles, more or less, of an article of food, labeled in part: "RelaKzpro . . . Rapid Relief . . . Herbal Dietary Supplement . . . 2 Fl. OZ. (60 ml) . . . Distributed by: Dordoniz Natural Products, LLC," Defendants *in rem.*	)	No. 16 CV 0076 Judge

VERIFIED COMPLAINT FOR FORFEITURE

The United States of America, by its attorney, Zachary T. Fardon, United States Attorney for the Northern District of Illinois, for its complaint states as follows:

1. This complaint requests seizure and condemnation of articles of food as described in the caption above ("the Articles"), in accordance with the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 301 *et seq.*

2. The United States brings this action *in rem* in its own right to condemn and forfeit the Articles. This court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and under 21 U.S.C. § 334, which provide this court with jurisdiction over seizures brought under the Act.

3. There are at 16050½ Woodmint Lane, South Beloit, Illinois, in the possession of Dordoniz Natural Products, LLC, and within the jurisdiction of this court, articles of food, as described in the caption, that consist in whole or in part of components that were shipped in interstate commerce from outside the State of Illinois.

4. This court has *in rem* jurisdiction over the Articles because they are located in the Northern District of Illinois. Upon filing this complaint, the United States requests this court issue an arrest warrant *in rem* pursuant to Federal Rule of Civil Procedure Supplemental Rule G (3)(b), which the United States will execute upon the Articles pursuant thereto.

5. The Articles are dietary supplements within the meaning of the Act, 21 U.S.C. § 321(ff), that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 331(a) because they are adulterated within the meaning of 21 U.S.C. §§ 342(f) and 342(f)(1)(B).

6. The Articles are subject to the notification requirement for dietary supplements that contain a new dietary ingredient, 21 U.S.C. § 350b(a)(2). Failure to submit such a notification renders the dietary supplements adulterated under 21 U.S.C. § 342(f). Specifically, the articles contain a new dietary ingredient, *Mitragyna speciosa*, also known as "kratom," for which the required notification has not been submitted.

7. Furthermore, the articles are adulterated under 21 U.S.C. § 342(f)(1)(B) in that they contain a new dietary ingredient, *Mitragyna speciosa*, for which there is inadequate information to provide reasonable assurance that this ingredient does not present a significant or unreasonable risk of illness or injury.

8. Serious concerns exist regarding the toxicity of kratom in multiple organ systems. Consumption of kratom can lead to a number of health impacts, including respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom consumption has been linked to neurologic, analgesic and sedative effects, addiction, and hepatic toxicity.

9. Mitragynine, the major alkaloid identified from kratom, has been reported as a partial opioid agonist, producing effects that are similar to morphine. Furthermore, a minor

alkaloid of kratom, 7-hydroxymitragynine, has been reported to be even more potent than morphine. Mitragynine and *Mitragyna speciosa* preparations have significant effects on cognition in humans.

10. *Mitragyna speciosa* has been indicated to have both narcotic and stimulant-like effects, which might substantiate its potential for abuse. Chronic exposure to *Mitragyna speciosa* preparations can be followed by withdrawal symptoms in humans, some typical withdrawal symptoms include hostility, aggression, excessive tearing, inability to work, aching of muscle, bones, and jerky limb movements.

11. By reason of the foregoing, the Articles are held illegally within the jurisdiction of this court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

WHEREFORE, the United States requests that a warrant of arrest for the defendant Articles as identified in the caption be issued; that notice be given to all persons having any interest in the Articles to appear herein and show cause why the seizure and condemnation should not be decreed; that judgment be entered declaring the defendant Articles be condemned and disposed of according to law; and that the United States be granted such other and further relief as this court may deem just and proper, together with costs of this action.

Respectfully submitted,

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VERIFICATION

I, Lauren Crivellone, Compliance Officer for the Food and Drug Administration, United States Department of Health and Human Services, declare under penalty of perjury that I have read the foregoing Verified Complaint for Forfeiture in this action and that the allegations it contains are true and correct to the best of my knowledge, information, and belief.

Executed January 5, 2016.

LAUREN CRIVELLONE
Compliance/Consumer Safety Officer
Food and Drug Administration
U.S. Department of Health and Human Services